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DEC 15 2009

Company	Crospon Ltd. Galway Business Park Dangan Galway, Ireland
Official Contact:	John O'Dea PhD
Proprietary or Trade Name:	EndoFLIP®
Common/Usual Name:	Gastrointestinal motility monitoring system
Classification Name:	FFX
Device:	EndoFLIP System and Catheter
Predicate Devices:	K991288 – G&J Electronics, Distender Series II Barostat K012232 – Sandhill Scientific, Insight Model S980000

Device Description:

The EndoFLIP® comprises a measuring system and a single use catheter to assist in measuring the stoma. In practice, the EndoFLIP® balloon catheter is attached to a syringe, pre-filled with a diluted saline solution, which is inserted into the syringe pump on the front of the EndoFLIP® system. The deflated balloon is inserted alongside an endoscope and introduced across the gastric band under direct visualization. Where available, fluoroscopy may be used to guide the catheter since the measurement electrodes are clearly visible in the image field. Once the balloon has been correctly located, it is then inflated with the diluted saline solution to a user programmed volume. The display shows the changes in the estimated stoma diameter as the gastric band is filled. The system also allows snapshots to be taken and compared to the real-time images.

Indications for Use:

The EndoFLIP® system is an endoscopically placed device indicated for use in patients fitted with a gastric band. The device is intended to estimate the size of the stoma produced by the gastric band in a clinical setting.

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Patient Population -- Patient undergoing gastric band surgery and post-operative band adjustment

Environment of Use -- Hospitals and sub-acute institutions, where gastric band procedures are performed

Contraindications -- The EndoFLIP® System is contraindicated where endoscopy is contraindicated

Device Attributes:

Design	
Principle of Operation	Syringe pump device that targets an inflate volume within a balloon inserted into the lumen of an organ. Provides an Estimated Diameter (D_{est}) of the balloon at 16 points along its length when inflated with custom conductive solution. Records balloon pressure via pressure sensor located in balloon.
	D_{est} electrodes are located at 16 points along the catheter inside a balloon. The balloon is placed such that it straddles the band stoma .
Energy Used And/Or Delivered	No electrical energy is delivered into the patient
Human Factors	Specified for 20 to 40^{o}C operating environment
	Touch screen user interface
	On screen keypad and external keypad interface provided
	Display is updated at 10 Hz.
Data Recording	Data is saved internally and can be exported to a USB mass storage device or printed to an attached USB printer
Electrical Safety	IEC60601-1 2nd Ed. + Am.1 + Am.2

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Mechanical Safety	Travel limits are detected by mechanical switches
	Syringe is automatically put in its home position at power on
	Balloon pressure alarm threshold defaults to 60mmHg with a maximum settable value of 150mmHg
	Maximum volume is set by the volume of solution in the syringe which is factory filled. This volume matches the balloon size on the catheter. The Balloon Inflate Volume cannot be set above the factory set syringe volume.
	The Deflate button is available after inflation has commenced. The syringe can be manually retracted at any time.
	Rigid syringe used to avoid potential volume errors
	Stepper motor driven lead screw is used to maintain accurate control over the syringe piston position. Piston movement resolution is 0.003175 mm (one step)
	No calibration required
Chemical Safety	Conductive solution inside balloon is diluted saline
Thermal Safety	Internal cooling fan with enclosure temperature monitoring. Alarm if temperature exceeds limits.
Materials	
Biocompatibility	All materials have passed biocompatibility tests in accordance with ISO 10993-1
Compatibility With The Environment And Other Devices	EndoFLIP operates with custom catheters only.
Sterility	Accessories are not supplied sterile, and are single patient use
Performance	
	Estimated balloon diameter (D_{est}) at 16 points in the balloon, displayed in numeric and graphical form, using the assumption that the balloon is symmetrical about its longitudinal axis at that electrode position. Range: 5 to 25 mm Resolution: 0.1 mm Accuracy: ± 1 mm rounded to nearest integer at 95% confidence
	Balloon pressure is measured and displayed: Range: -10 to 100 mmHg Resolution: 0.1 mmHg Accuracy: ± 1 mmHg at 95% confidence
	Balloon volume is displayed: Range: 0 to 50 mL Resolution: 1 mL Accuracy: ± 5 mL

Differences Between Other Legally Marketed Predicate Devices

The EndoFLIP® system is viewed as substantially equivalent to the predicate devices listed above.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

DEC 15 2009

Crospon Ltd.
c/o Mr. Paul Dryden
President
ProMedic, Inc.
24301 Woodsage Drive
BONITA SPRINGS FL 34134-2958

Re: K092850
Trade/Device Name: EndoFLIP® System
Regulation Number: 21 CFR §876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: FFX
Dated: September 15, 2009
Received: September 16, 2009

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: _____ (To be assigned)

Device Name: EndoFLIP® System

Indications for Use:

The EndoFLIP® system is an endoscopically-placed device indicated for use in patients fitted with a gastric band. The device is intended to estimate the size of the stoma produced by the gastric band in a clinical setting.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K092850